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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,646	03/23/2001	Scott H. Jaeger	11506/3	4634

7590
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400 Cleveland Boulevard
Haddonfield, NJ 08033

EXAMINER

KOPPIKAR, VIVEK D

ART UNIT	PAPER NUMBER
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3686

MAIL DATE	DELIVERY MODE
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05/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/815,646	Applicant(s) JAEGER ET AL.	
	Examiner VIVEK D. KOPPIKAR	Art Unit 3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/16/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8 and 19-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8 and 19-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

1. Claims 8 and 19-42 have been examined in this application. This communication in response to the Petition filed on March 16, 2009 to revive the application from abandonment.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 8, 19-36 and 41-42 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims are directed towards a method for determining an overall confidence level for medical clinical conclusions but the claims do not recite a device (e.g. a computer) which is used for carrying out the method. Therefore, these claims are not tied to a statutory class of invention. In order to overcome this rejection, the Office recommends amending the claims so that they recite a device (e.g. a computer) which is used in carrying out the claimed method. The applicants are reminded, however, that any amendment(s) to the claim(s) must have support in the specification as it was originally filed.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 8 and 19-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Step (h) of claim 8 does not appear to be enabled in the specification as the specification does not specify the step of generating an overall confidence parameter for the selected medical clinical conclusion as a ratio of a first product of the first impact parameter and the first confidence parameter to a second product of the second impact parameter and the second confidence parameter.

Also, it is not clear how the membership function, recited on page 18, line 4 relates to the overall confidence parameter. Finally, it appears that the “second product of the second impact parameter and the second confidence parameter” is the area of the best-case conclusion analysis. The Office recommends amending Claim 8 to set forth that the second product is the product of the best-case conclusion analysis.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are indefinite because Claim 34 recites a formula for determining the overall level of confidence of the conclusion, however, all the variables recited in the formula are not defined in the body of the claim

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so it is not clear exactly what the formula entails. Appropriate correction and/or clarification is required.

For the purposes of the examination, the Office will broadly interpret Claim 34 to encompass any teaching in the prior relating to the determination of the overall confidence parameter of a conclusion, regardless of the manner in which the confidence parameter is determined or calculated.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 8 and 19-42 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication 2003/0105731 to LaPointe.

(A) As per claim 8, Lapointe et al. discloses a method for determining an overall level of confidence for a medical conclusion (i.e. risk of preterm delivery) comprising the steps of:

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- a. storing a plurality of possible clinical conclusion (i.e. risk of preterm delivery), (Lapointe, page 23, paragraph 0416, Figs 12,13, outputs A, B, Fig. 14, outputs C, D).
- b. storing a plurality of medical essential elements (i.e. clinical data, patient's variables, patient history information.) (Lapointe et al., page 8, paragraph 0097, page 21, paragraphs 0034-0360).
- c. selecting at least one medical essential element from the plurality of medical essential elements and selecting one medical clinical conclusion from the plurality of medical clinical conclusions (LaPointe: Page 8, Paragraph [0097] and Page 21, Paragraphs [0034]-[00360]).
- d. generating a first confidence parameter representing a degree of relationship between the medical essential element and the medical clinical conclusion (Lapointe et al., page 1, paragraph 0008, page 10, paragraphs 0110, 0112, 0116).
- e. generating a first impact parameter representing a weight of a medical essential element pointing toward a medical clinical conclusion (LaPointe et al., page 4, paragraph 0027).
- f. generating a second impact parameter corresponding to the selected medical clinical conclusion (LaPointe et al., page 1, paragraph 0008, page 10, paragraphs 0110, 0112, 0116).
- g. generating a second confidence parameter corresponding with the selected medical clinical conclusion (LaPointe et al., page 1, paragraph 0008, page 10, paragraphs 0110, 0112, 0116).
- h. generating an overall confidence parameter for the selected medical clinical conclusion as a ratio of a first product of the first impact parameter and the first

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confidence parameter to a second product of the second impact parameter and the second confidence parameter, wherein the second product represents a best-case scenario for the medical clinical conclusion (LaPointe et al., page 1, paragraph 0008, page 10, paragraphs 0110, 0112, 0116).

(B) As per claims 19-42, these claims are substantially similar to Claim 8 and therefore, these claims are rejected in the same manner as claim 8, which is set forth above.

Response to Arguments

8. Applicant's arguments filed on March 16, 2009 with respect to the pending claims have been considered but are moot in view of the new grounds of rejection.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Jerry O'Connor, can be reached at (571) 272-6787. The fax telephone numbers for this group are either (571) 273-8300 or (703) 872-9326 (for official communications including After Final communications labeled "Box AF").

Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,

/Vivek D Koppikar/

Examiner, Art Unit 3686

5/5/2009